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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,452	06/09/2005	Yixian Qin	788-20-PCT-US (R7450)	8706

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EXAMINER	
BOR, HELENE CATHERINE	

ART UNIT	PAPER NUMBER
3768	

MAIL DATE	DELIVERY MODE
09/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,452	QIN ET AL.	
	Examiner	Art Unit	
	HELENE BOR	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03/10/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 June 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claim 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazess (US Patent No. 5,840,029) and further in view of Fatemi'98 (Fatemi, M.; Greenleaf, J.F., "Coherent ultrasound stimulated acoustic emission imaging," *Ultrasonics Symposium, 1997. Proceedings., 1997 IEEE* , vol.2, no., pp.1411-1414 vol.2, 5-8 Oct 1997).

Claim 1, 21 & 29: Mazess teaches ultrasonic system for determining at least one property of bone (Abstract). Also Mazess teaches the use of a processor for determining tissue properties based on the received ultrasound signal (Figure 4, Element 41). Mazess teaches the transducers configured to receive the bone sample therebetween (Figure 4, Element 21 & Col. 7, Line 13-17). Mazess fails to teach confocal transducers. However, Fatemi teaches a system for using confocal transducers to receive and transmit the ultrasound to result in a highly localized/focused oscillating force (Page 1411, Right Column, Abstract). It would have been obvious to one of ordinary skill in the art to modify the system of Mazess to include the confocal transducers as taught by Fatemi to result in a highly localized/focused oscillating force (Page 1411, Right Column, Abstract).

Claim 2 & 28: Mazess teaches the bone sample is a bone in a live human being (Col. 2, Line 27-33).

Claim 3, 9, 22 & 25: Mazess teaches a system capable of high resolution (Col. 3, Line 3-5) but fails to specify a specific range. However, Fatemi teaches a system wherein the spatial resolution is equal to approximately 0.5 (Page 1412, Right Column, Simulation).

Claim 4: Mazess teaches a system wherein the transmitting transducer emits ultrasonic signals at a frequency on the order of tens of megahertz (Col. 9, Line 46-52).

Claim 5 & 24: Mazess teaches using the system for three dimensional grid (x, y, and z plane) and moving the transmitting and receiving transducers in three dimensions (Col. 27, Line 41-44 & Col. 27, Line 61 – Col. 28, Line 6).

Claim 6: Mazess teaches the processor initiating an ultrasonic signal from the transmitting transducers that is transmitted through the bone sample and received by the receiving transducer (Figure 4, Element 38). Kantorovuch teaches the processor receiving a signal reflecting one or more measures of the received ultrasonic signal (Col. 5, Line 34-50). Mazess teaches the processor further determining the at least one bone property at each point of the sample based upon the at least one ultrasonic parameter for the point (Col. 5, Line 50-57).

Claim 7 & 8: Mazess teaches the three dimensional scanning stage (Col. 27, Line 40-44) wherein it is able of discrete scans, continuous scans and other methods of use that the clinician desires can be selected by a selectable switch (Col. 6, Line 32-67).

Claim 10: Mazess teaches a system wherein the at least one ultrasonic parameter determined for the at least one point of the sample are ultrasonic velocity

(UV) and a measure of ultrasonic attenuation (UA) (Col. 11, Line 17-21, Col. 13, Line 33-37 & Col. 19, Line 17-26 & 50-58).

Claim 11: Mazess teaches a system wherein ultrasound velocity (Abstract) at the at least one point of the sample is calculated by the processor (Figure 4, Element 41). Mazess teaches using the time delay, the thickness of the bone and the velocity of the ultrasound in the medium (Col. 12, Line 65-67 & Col. 19, Line 17-26 & 50-58).

Claim 12, 14, 16 & 19: Mazess goes into detail regarding the applicant defined ATT, although Mazess does not use the term ATT. Mazess states that ultrasound attenuation is dependent on bone mineral density and the integrity being tested (Col. 9, Line 26-54). Mazess teaches a system wherein the ATT at the at least one point (x,y,z) of the sample is calculated by the processor from the energy of the received ultrasound signal as passed through the bone sample and the energy of a reference ultrasound signal received without the sample positioned between the transducers (Col. 9, Line 5-39). Mazess states that ultrasound attenuation is dependent on bone mineral density and the integrity being tested (Col. 9, Line 26-54). In addition, Mazess teaches a system capable of determining stiffness (Col. 27, Line 38-39). Mazess does teach a system capable of measuring both the trabecular and cortical bone and both reading providing distant data about the bone (Col. 27, Line 38-39).

Claim 13: Mazess teaches using the system for three dimensional grid (x, y, and z plane) (Col. 27, Line 40-44). Mazess teaches a system where the BUA at the at least one point (x,y,z) of the sample is calculated by the processor (Figure 6, Element 38) as the slope of the linear section of the ultrasound attenuation coefficient function,

$UAC_{(x,y,z)}$ (f), where $UAC_{(x,y,z)}$ (f) is calculated from the fast fourier transform (FFT) of frequency f (as a function of time) for the received ultrasound signal f_{bone} (t) as passed through the bone sample and a reference (Col. 11, Line 10-16). Ultrasound signal f_{ref} (t) received without the sample positioned between the transducers in accordance with the equation (Col. 9, Line 8-10).

Claim 15 & 27: Mazess teaches where at least one bone property determined at the at least one point is bone mineral density (BMD) (Figure 26, Element 418 & Col. 28, Line 30-39).

Claim 17, 20 & 26: Mazess teaches using linear regression constants predetermined by conducting a regression analysis between measurements of BUA on bone specimens and BMD measurements on the bone specimens using conventional analysis (Col. 11, Line 9-16). In addition, Mazess teaches the use of UV (Col. 19, Line 17-49) and ATT (Col. 9, Line 26-54) for determining the BMD.

Claim 18: Mazess teaches a system wherein the at least one bone property determined at the at least one point is Stiffness (Col. 27, Line 30-40). The applicant defines Stiffness as "From the tissue level regions of bone that experience relatively high stiffness tend more towards cortical bone. Regions of bone experiencing low Stiffness tend to be more trabecular" (Page 3). From the applicant's admission, stiffness is related to the amount of either the cortical or trabecular bone. While Mazess does not explicitly use the word stiffness, Mazess does teach a system capable of measuring both the trabecular and cortical bone and both reading providing distant data about the bone (Col. 27, Line 38-39). Mazess also cites an article by Lees stating

"[V]arious studies involving attenuation and speed of sound measurements in both cortical and spongy (cancellous or trabecular) bone....The transit time of an acoustic signal through a bone member therefore are proportional to the bone density" (Col. 2, Line 3-12).

Claim 23: Mazess fail to teach the confocal point. However, Fatemi teaches the confocal point and acoustic emission signal to result in a highly localized/focused oscillating force (Page 1411, Right Column, Abstract).. Mazess teaches repositioning the point to a new point of interest in the material sample (Col. 28, Line 1-6). Mazess teaches repeating steps for the new point of interest in the material sample (Col. 28, Line 1-6).

Response to Arguments

3. Applicant's arguments with respect to claim 1-29 have been considered but are moot in view of the new ground(s) of rejection. The Applicant argued that Mazess fails to cure the defect of Kantorovuch and Fatemi. However, the Examiner respectfully disagrees. The Examiner contends that Mazess does teach the sample therebetween.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELENE BOR whose telephone number is (571)272-2947. The examiner can normally be reached on M-T 8:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. B./
Examiner, Art Unit 3768

/Eric F Winakur/
Primary Examiner, Art Unit 3768